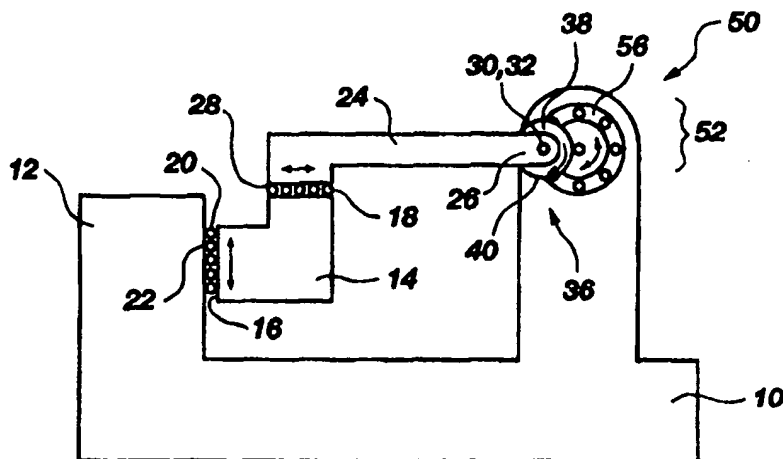




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(54) Title: METHOD AND APPARATUS FOR FORMING CUTS IN CATHETERS, GUIDEWIRES AND THE LIKE (57) Abstract <p>A catheter, guidewire or other cylindrical object cutting device which includes a base, at least one circular saw blade mounted on a spindle member, and a clamp for manipulating the object to be cut. The at least one circular saw blade is rotatably mounted on the spindle member. The spindle member is free to move vertically and horizontally with respect to the base to thereby control the location, size and depth of the cuts in a cylindrical object disposed adjacent thereto. The clamp is able to hold the object to be cut, as well as rotate it to expose the entire circumference of the object to the saw blade. By releasing the clamp, a pinch roller can advance the object before the clamp is re-engaged to securely hold the object for cutting. Sensors are also provided to enable detection of wear of the saw blade so as to signal needed replacement or adjustment of the saw blade to compensate.</p>		



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METHOD AND APPARATUS FOR FORMING CUTS IN CATHETERS, GUIDEWIRES AND THE LIKE

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BACKGROUND**1. Field of the Invention**

The present invention pertains to making precision cuts in catheters and guidewires. Specifically, a device
15 for holding, advancing, rotating and then cutting a catheter or guidewire is provided which is able to manipulate the catheter or guidewire in two degrees of freedom to enable precision control of the location of the cuts. Various clamping mechanisms are provided for
20 manipulating the catheter or guidewire, as well as mechanisms for wear detection of saw blades used to make the cuts resulting in controlled variation in mechanical properties.

25 2. State of the Art

Making cuts in catheters and guidewires requires precision in order to ensure reliability because of the medical applications in which they are used. However, it is also important to control costs of production so that
30 costs to the health care industry can be minimized.

The state of the art is typified by such devices as grinding wires, wound coils, and lasers for making the cuts. But these devices often suffer from high cost or imprecise or difficult control mechanisms for properly

positioning both the device to make the cut and the cylindrical object to be cut.

What is needed is a method and apparatus for making cuts in catheters and guidewires which allows
5 precise control of characteristics of the cuts. This entails precision holding, advancement and rotation of the generally cylindrical object while at least one saw blade is itself advanced to make the cut and retracted afterward.

10

OBJECTS AND SUMMARY OF THE INVENTION

It is an object of the present invention to provide a method and apparatus for forming precision cuts in catheters and guidewires.

15 It is another object to provide a method and apparatus for forming precision cuts in cylindrical objects.

It is yet another object to provide a method and apparatus for forming precision cuts by manipulating a
20 cylindrical object in two degrees of freedom to control the parameters of the cuts.

It is still another object to provide a method and apparatus for holding, advancing and rotating a cylindrical object to be cut.

25 Still yet another object of the invention is to provide a method and apparatus for increasing throughput of a device which forms cuts in cylindrical objects by providing multiple saw blades on a single cutting tool.

30 It is another object to provide a method and apparatus for detecting the extent of wear of a saw blade in order to more precisely control the position of the saw blade.

35 These and other objects of the present invention are realized in a preferred embodiment of a device for making cuts in a catheter, guidewire or other cylindrical object. The device includes a base which

has at least one circular saw blade mounted on a spindle member, and a clamp for manipulating and positioning the object to be cut. The circular saw blade is rotatably mounted on the spindle member. The
5 spindle member is free to move vertically and horizontally with respect to the base to thereby control the location, length, depth and angle of the cuts in a cylindrical object disposed adjacent thereto. The clamp is able to hold the object to be
10 cut, as well as position it by, for example, rotation to thereby expose the entire circumference of the cylindrical object to the saw blade. By releasing the clamp, a pinch roller advances the cylindrical object before the clamp is re-engaged to securely hold the
15 cylindrical object for cutting.

Another aspect of the invention is the ability to make precision cuts by providing means for controlling the rotation and advancement of the object to be cut and movement of the saw blade spindle member. Sensors
20 are also provided to enable detection of wear on the saw blade so as to signal needed replacement or adjustment of the location of the saw blade spindle member to compensate.

Another aspect is the ability to simultaneously
25 make a plurality of cuts in the object. This is accomplished with a saw blade having a plurality of blades in parallel. Even more cuts can be made by providing more than one saw blade spindle member, where each is independently movable in two degrees of
30 freedom.

Another aspect of the invention is to provide more than one spindle member so that blades can simultaneously make precision cuts at different locations along the length of the cylindrical object.

35 These and other objects, features, advantages and alternative aspects of the present invention will become apparent to those skilled in the art from a

consideration of the following detailed description taken in combination with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Figure 1A is a front elevational view of a preferred embodiment made in accordance with the principles of the present invention.

 Figure 1B is a side elevational view of the invention shown in Figure 1A.

10 Figure 2 is an alternative embodiment of a vertically moving member shown reversed in orientation with respect to FIGS 1A and 1B.

 Figure 3 is an alternative embodiment of a horizontally moving member shown reversed in
15 orientation with respect to FIGS 1A and 1B.

 Figure 4 is a block diagram of the preferred embodiment which shows a control means and sensor means for controlling position determination and movement of components.

20 Figure 5 is a block diagram showing signals which pass between components when using an electrical conduction sensor.

 Figure 6 is a block diagram showing signals which pass between components when using a mechanical drag
25 detection sensor.

 Figure 7 is a block diagram showing signals which pass between components when using a rotation detector sensor.

 Figure 8 is a block diagram showing signals which
30 pass between components when using an optical detection sensor.

 Figure 9A is a front elevational view of an alternative embodiment for the clamping means.

 Figure 9B is a side elevational view of the
35 alternative embodiment for the clamping means of FIG. 9A.

Figure 10 is an alternative saw blade assembly which can be used in all embodiments of the present invention.

Figure 11A is a top elevational view of an alternative clamping device.

Figure 11B is a side elevational view of the alternative clamping device of FIG. 11B.

Figure 12 is an alternative embodiment which uses two saw blade assemblies to simultaneously make incisions in the catheter.

DETAILED DESCRIPTION OF THE INVENTION

Reference will now be made to the drawings in which the various elements of the present invention will be given numerical designations and in which the invention will be discussed so as to enable one skilled in the art to make and use the invention.

The present invention is illustrated in FIGS. 1A and 1B. FIG. 1A is a front view of the preferred embodiment of the invention, and shows the system for forming precision cuts in a catheter, a guidewire, or other cylindrical objects. For purposes of keeping in mind the intended use of the present invention, a catheter will be referred to as the object being cut, although any cylindrical object can be substituted for the catheter. However, reference to the catheter is only for the convenience of writing in terms of a specific cylindrical object, and should not be considered a material limitation of the invention. However, referring to a catheter keeps present in mind the objective of having a very precise cutting device, where precision is paramount in most medical applications. Furthermore, a catheter is only one embodiment of a medical application, but which easily represents the need for precision.

The system 6 shown in FIGS. 1A and 1B is comprised of several elements including a base member

10 for supporting the structure. Coupled in sliding engagement with a vertical base member 12 is a vertically movable member 14 which has a first vertical coupling face 16 and a first horizontal coupling face 18. The vertical coupling face 16 is smilingly engaged with a base member vertical coupling face 20.

The mechanism 22 for enabling the sliding engagement between the vertical coupling face 16 and the base member vertical coupling face 20 can be any appropriate apparatus. The important consideration is that the vertically movable member 14 not be permitted to move horizontally, or the precision of the system will be compromised. Therefore, the tolerances of the mechanism 22 must necessarily be small. A good example of an appropriate mechanism 22 is well known to those skilled in the art as a crossed roller bearing slide.

The shape of the vertically movable member 14 is shown here as a small backwards "L". An alternative shape for the vertically movable member 14 is shown in FIG. 2. The member 14 is flipped over as compared to the embodiment of FIG. 1A. The important feature of the member 14 is that it provide two faces 16, 18 which can be slidably engaged to move vertically and provide a second face on which another member can slidably engage to move horizontally.

The system in FIGS. 1A and 1B is also comprised of a horizontally movable member 24 which has a spindle end 26 and a second horizontal coupling face 28. This horizontally movable member 24 is slidably engaged at its second horizontal coupling face 28 to the vertically movable member 14 at its first horizontal coupling face 18. It should be observed that the vertically movable member 14 and the horizontally movable member 24 are capable of moving independently of each other. In this way, the system

achieves two independent degrees of freedom of movement.

The spindle end 26 of the horizontally movable member 24 provides a horizontal slot 30 in which a spindle 32 is disposed. The slot 30 is generally circular to serve as a receptor for the round shaft 34 of the spindle 32. The spindle shaft 34 has disposed on a working end 36 thereof at least one circular saw blade 38. The circular saw blade 38 is disposed vertically on the spindle shaft 34, but may also be angled in other embodiments.

The spindle shaft 34 is coupled to a drive motor by gears, belts, direct drive, or any other appropriate means (not shown) which will cause the spindle shaft 34 to rapidly rotate. The drive motor (not shown) can be disposed in any appropriate location relative to the spindle shaft. In a preferred embodiment, the spindle shaft 34 is driven by a brushless DC motor through a toothed timing belt.

The circular saw blade 38 is typical of those found in the art. In a preferred embodiment, the cutting edge 40 of the saw blade 38 is coated with industrial diamonds.

The means for holding and otherwise manipulating a catheter 8 to be cut is the clamping member 50. The clamping member 50 is comprised of two major assemblies: the clamp 52 and the clamp feeding (supplying) means 54, or the device which feeds the catheter 8 to and then through the clamp 52. The clamping member 50 is also coupled to the base member 10 and disposed to hold the clamp 52 in a position for easy feeding of the catheter 8 to the circular saw blade 38.

In the preferred embodiment, the clamp 52 is of the type known to those skilled in the art as a collet clamp. A collet clamp is a slotted cylindrical clamp inserted tightly into the tapered interior of a sleeve

or chuck on a lathe to hold a cylindrical piece of work. In FIG. 1A the cylindrical shape of the clamp 52 is visible. It is slotted in that the clamping arms 58 are separate from each other so that they can pull away from the catheter 8 when disengaging, and then securely come together around the catheter 8 when engaging.

In a preferred embodiment, a desirable feature of the clamp 52 is that it is rotatably mounted within the clamping member 50. The collet clamp 52 can then rotate so as to dispose a different portion of the surface of the catheter 8 to the saw blades 38. The mechanism for rotating the clamp 52 is shown generally at 56, and is comprised of the clamp 52 which is held in a frame which can rotate with respect to the saw blade 38.

The clamp feeding (supplying) means 54 seen in FIG. 1B is shown in this preferred embodiment to be comprised of a pinch roller assembly 60, 62 working in conjunction with a feed roller 66. As FIG. 1B should make clear, the pinch roller assembly 60, 62 feeds the catheter 8 to the clamp 52 by using friction created between two opposing members 60, 66. The upper member is the pinch roller 60. The lower member is the feed roller 66. The feed roller 66 has an axle 68 mounted in the clamp feeding means 54 so that the feed roller 66 can roll. The pinch roller 60 is disposed at the end of a lever arm 62 which pivots at a pivoting end 70. Located distally from the pinch roller assembly along the length of the lever arm is a hole 72. One end of a spring 64 is inserted therethrough, and the other end of the spring 64 is coupled at another hole 74 to the clamp feeding means 54. The spring 64 provides the tension necessary for the feed roller 64 to push the catheter 8 to the clamp 52.

Having described most of the components in a preferred embodiment of the catheter cutting assembly

6, the operation of the assembly 6 is as follows. First, the uncut catheter 8 is placed between the pinch roller 60 and the feed roller 66. This can be done by raising the lever arm 62 by stretching the spring 64. Releasing the lever arm 62 causes the pinch roller 60 to push down against the feed roller 66, with the catheter 8 disposed therebetween. A drive mechanism (not shown) is coupled to the feed roller 66 to cause it to roll and thereby push the catheter 8 toward the clamp 52. The clamp 52 should be in a disengaged position (hole through clamp is larger than diameter of the catheter 8) so that the catheter 8 can be fed easily therethrough. After passing through the clamp 52, the catheter 8 is fed sufficiently far past the circular saw blade 38 so that it is in a proper position to have an incision made in or through its surface.

When the catheter 8 is positioned correctly, the clamp 52 is engaged and the saw blade 38 is advanced to make cutting contact. Before cutting, the saw blade 38 will always be positioned in a retracted position. The retracted position is both vertically below and horizontally pulled away from the catheter 8. The first movement of the saw blade 38 is 1) horizontal advancement toward the catheter 8. This is accomplished by moving the horizontally movable member 24 relative to the vertically movable member 14 to which it is attached. The horizontally movable member 24 is moved until it has reach the depth of the incision to be made in the catheter 8. The next step 2) comprises the vertically movable member 14 moving upwards relative to the base 10 to which is coupled to thereby make the cut. The saw blade 38 is then immediately retracted by moving the vertically movable member 14 away from the catheter 8. The horizontal member is moved only when the next cut is at a different depth or when all cutting is complete.

If another cut is to be made, the collet clamp 52 is released as step 4). The catheter 8 is then fed through the clamp 52 by the feed roller 66 as step 5). The collet clamp 52 is then re-engaged in step 6) and, if necessary, the collet clamp 52 is rotated to expose a different position of the catheter 8 to the saw blade 38. The saw blade 38 is then moved horizontally if the depth of cut is to change, and then vertically to make the cut and steps 1) through 7) repeat as often as necessary until all the incisions have been made or the catheter 8 is no longer capable of being grasped by the feed roller 66 and opposing pinch roller 60.

The above description of the operation of the catheter cutting system 6 describes the different roles served by the clamp 52. When the circular saw blade 38 is making a cut in the catheter 8, the clamp 52 holds the catheter 8 steady. When the cut has been made in the catheter 8, the catheter 8 is fed through the clamp 52 by causing the clamp to disengage from around the catheter 8. After being disengaged, the catheter 8 is fed through the clamp 52 until the next incision point on the catheter 8 is in position relative to the saw blade 38. The clamp 52 re-engages so as to be disposed snugly around the catheter 8 to again prevent movement of the catheter 8 during cutting.

It should be recognized from the description above that the width of a cut into the catheter 8 is limited to the width of the circular saw blade 38. A wider cut therefore requires that the catheter 8 be advanced slightly past the saw blade 38. However, advancement does not take place while making a cut. The saw blade 38 must be withdrawn so that the clamp 52 can disengage from around the catheter 8 while it is advanced. This is necessary because allowing

cutting of the catheter 8 when the clamp is disengaged would create a useless if not imprecise cut..

Another vital component of the assembly 6 is a position sensing means. While it is now understood
5 how the catheter 8 is cut, it is not been explained how the feed roller 66 knows when to stop feeding the catheter 8 through the clamp 52, or how far the clamp 52 needs to rotate before cutting commences. In other words, precision cutting also requires precision
10 positioning of the catheter. Precise positioning requires sensors which can detect where the catheter 8 is in relation to the saw blade 38 and the clamp and then provide this information to some control device which coordinates movement of all components by
15 sending the necessary signals to correctly position all of the system 6 components.

This concept is shown generally in the block diagram of FIG. 4. The catheter cutting system 6 is shown as having inputs from a control means 80 for
20 positioning the vertically movable member 14 and shown as arrow 82, the input shown as arrow 84 for positioning the horizontally movable means 24, the arrow 86 which designates an input for controlling rotation of the clamp 52, and an arrow 88 which
25 designates an input for controlling the feed roller 66. Two control inputs for the clamp and the spindle motor are also shown as arrows 87 and 89, respectively. The block diagram in FIG. 4 also shows a sensor means 90 for receiving position information
30 from the system 6 as indicated by arrow 92. This information is transmitted to the control means 80 as indicated by arrow 94 so that it can be processed and the correct control signals 82, 84, 86, and 88 can be transmitted to the system 6.

35 There are several alternative methods for determining the position of the catheter 8 relative to the saw blade 38. These devices can all be

substituted as the sensor means 90 of FIG. 4. The first device is an electrical conduction sensing circuit 100 shown in block diagram form as FIG. 5. It is sometimes the case that the materials used in catheters 8 are electrically conductive. Furthermore, the saw blade 38 can also be electrically conductive. Consequently, bringing the saw blade 38 into contact with the conductive catheter 8 can result in the completion of an electrical circuit. By moving the saw blade 38 sufficiently slowly so as not to abruptly make contact with the catheter 8, the moment of contact can be used as a reference point so that the saw blade 38 can be moved the proper horizontal distance to make the desired cut.

FIG. 6 shows an alternative method of position sensing. In this embodiment, mechanical drag detection means is coupled to the saw blade 38. The drag detection means 102 can be coupled to either the driving means 104 of the saw blade 38, or the spindle 32 of the saw blade 38. In other words, the drag detection means 102 is any suitable device for detecting when a dragging force is encountered by the saw blade 38. For example, one device for this purpose is a torque transducer which measures the torque loading of the shaft which turns the blade 38.

FIG. 7 shows a related method of position sensing is to use a rotation detector means 106 which detects even slight partial revolutions of the saw blade 38 as the spindle is oscillated vertically and slowly advanced horizontally. With the blade 38 not spinning, rotation of the blade 38 will occur when slight contact is made between the blade with the catheter.

A final embodiment for detecting the position of the saw blade 38 relative to the catheter 8 is to use an optical detector 108, as shown in block diagram form in FIG. 8. The optical detector means 108 is

disposed such that it can detect contact between the saw blade 38 and the catheter 8. There are various optical devices which can be used to implement this detector 108.

5 One aspect of the invention which is related to the various sensing means 90 described above is that not only is it important to know the position of the blade, but it is also important to know the degree of wear of the blade. All of the sensor embodiments
10 above are inherently able to compensate for the wear which the blade 38 will experience. In other words, none of the methods for determining the exact position of the blade 38 rely on an assumption that the size of the blade 38 is constant. All of the sensor
15 embodiments 90 account for saw blade 38 wear by dynamic determination of position which is not based on a predefined size of the saw blade 38. Instead, the sensors 90 determine when contact is being made, and adjust the position of the blade 38 or the
20 catheter 8 accordingly.

 Variations of the preferred embodiment are illustrated in FIGS. 9A and 9B which show that the clamping means 52 has been modified. As can be seen in FIG. 9A, a stationary support surface 110 is
25 provided with a slot 112 therein for supporting the catheter 8 from below. The slot 112 guides and holds the catheter 8 before, during and after cutting. Holding the catheter 8 not only allows more precise cutting, but prevents damage to the catheter 8 which
30 might otherwise occur. A movable clamping member 114 or anvil is also provided to thereby apply force to the catheter 8 which is clamped between the anvil 114 and the slotted support surface 110. FIG. 9B also shows that the anvil 114 has a mechanism 116 which
35 allows the anvil 114 to move vertically with respect to the support surface 110.

FIG. 10 illustrates a modification to the spindle 32 and saw blade 38 arrangement shown in FIGS. 1A and 1B. Specifically, a plurality of saw blades 38 are shown as being mounted in parallel on the same spindle 32. This also means that the saw blades 38 are necessarily coaxial. It is also preferred that the saw blades 38 have the same diameter so that no individual saw blade 38 makes a deeper incision in the catheter 8 than any of the others. However, it should be apparent that if the spindle 32 or the saw blades 38 are easily detachable from the system 6, then saw blades of varying diameters might be mounted on the same spindle 32 to achieve a consistent pattern of cuts having different depths.

FIG. 11A shows a clamp mechanism 120 which should be used in conjunction with the multiple saw blade 38 assembly of FIG. 10. The clamp mechanism 120 is capable of holding a catheter 8 in place while the catheter 8 is cut by the plurality of saw blades 38. This is accomplished by providing a clamping surface 122 having a depression or slot 124 for receiving the catheter 8. Coupled to the clamping surface is a leaf spring 126. The leaf spring 126 is comprised of several fingers 128 which force the catheter 8 to remain in the slot 124 while it is cut. Disposed perpendicular to the slot 124 and extending from the clamping surface 122 completely through the clamping mechanism 120 to a back side 136 are a plurality of slots 130 (which make clamp fingers 132) through which the saw blades 38 are extended to thereby cut the catheter 8. The fingers 128 of the leaf spring 126 are typically spaced apart a distance which is equal to the spacing between the plurality of slots 130. This ensures that the saw blades 38 do not inadvertently make contact with the leaf spring fingers 128 while cutting the catheter 8.

To allow the catheter 8 to be fed through the slot 124 in the clamping surface 122, there must be a mechanism for raising the fingers 128 of the leaf spring 126 from off the clamping surface 122. FIG. 11A shows a plurality of holes 134 through the clamping mechanism 120, one hole 134 per clamp finger 132. FIG. 11B shows these holes 134, and more importantly, the plurality of push rods 136 which extend through the holes 134 from the back side 136 of the clamp mechanism 120 to the clamping surface 122. What is not shown is a lever arm or other mechanism which simultaneously pushes the plurality of push rods 136 when the clamp mechanism 120 is instructed to disengage the clamp and move the catheter 8.

FIG. 12 is an illustration of another alternative embodiment of the present invention. The vertically movable member 14 is shown having another shape which enables it to have disposed thereon two horizontally movable members 24, each having its own associated saw blade or blades 38. This embodiment enables the catheter 8 to be simultaneously cut at different circumferentially defined points on the catheter surface. This is especially useful in making cuts in catheters which having multiple incisions. for example, on diametrically opposed positions on the catheter 8.

It should be noted that while the preferred embodiment has been defined as having a horizontally movable member with the spindle for the saw blade coupled thereto, the placement of the vertically and horizontally movable members can be switched. In this arrangement, the horizontally movable member is coupled to the base member and the vertically movable member, and the vertically movable member has a spindle rotatably coupled thereto.

An alternative embodiment of the present invention uses a lever arm which is capable of

movement in at least two degrees of freedom so that it can move vertically and horizontally to position a spindle end.

Another aspect of the invention which should be clarified is that rotating the catheter is not limited to using a rotatable clamping mechanism. For example, the clamp can be non-rotatable and disengaged to enable the catheter feeding mechanism to rotate the catheter, and then reengage the clamp to make additional incisions. Furthermore, the clamp and the catheter feeding mechanism can be rotated together before additional incisions are made.

Alternative aspects of the invention include the substitution of a non-mechanical cutting instrument for the rotating blade of the presently preferred embodiment. For example, a laser can be provided for cutting through materials which are mounted on the system.

It should also be realized that rotating blades are not the only type of mechanical blade which can be utilized. Conventional "sawing" blades can also be provided.

It is to be understood that the above-described embodiments are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention. The appended claims are intended to cover such modifications and arrangements.

CLAIMS

What is claimed is:

1. A system for forming at least one precision cut in an elongate object such as a catheter or a
5 guidewire, wherein the precision cut is generally at an angle or transverse relative to a lengthwise axis of the elongate object, said system comprising:
a securing means for repeatedly releasing and then holding the elongate object in a position
10 suitable for cutting the elongate object at an angle or transversely relative to the lengthwise axis;
a manipulating means for moving the elongate object so that it can be disposed in the position suitable for cutting when it is released by the
15 positioning means; and
a cutting means for forming the at least one precision cut in the elongate object to any desired depth.
- 20 2. The cutting system as defined in claim 1 wherein the cutting means further comprises a means for moving the cutting means relative to the elongate object being held by the positioning means such that the precision cut can be made at an angle or transversely
25 relative to the lengthwise axis of the elongate object.
3. The cutting system as defined in claim 1 wherein the securing means for repeatedly releasing and then
30 holding the elongate object is further comprised of a clamping device for securing the elongate object after being manipulated into a correct position for cutting by the cutting means, said clamping device having at least two opposing surfaces which are movable so as to
35 press against the elongate object which is disposed therebetween and hold the elongate object immobile.

4. The cutting system as defined in claim 3 wherein the manipulating means for moving the elongate object so that it can be disposed in the position suitable for cutting is further comprised of a feeding device
5 for manipulating the elongate object relative to the securing means so as to be in a correct cutting position with respect to the cutting means, wherein the manipulation of the elongate object is any appropriate action which includes pushing, pulling and
10 turning the elongate object with respect to the cutting means and the securing means.
5. The cutting system as defined in claim 3 wherein the clamping device is further comprised of means for
15 rotating the clamping device while it is holding the elongate object immobile and while the cutting means is cutting the elongate object.
6. The cutting system as defined in claim 1 wherein
20 the cutting means is selected from the group of cutting means consisting of a mechanical blade and a laser.
7. The cutting system as defined in claim 6 wherein
25 the mechanical blade is selected from the group of mechanical blades consisting of rotating saw blades and non-rotating saw blades.
8. The cutting system as defined in claim 1 wherein
30 the securing means, the manipulating means, and the cutting means are movable and securable in a position with respect to each other, such that the elongate object can be positioned for cutting at a desired angle by the securing means and the manipulating means
35 with respect to the cutting means.

9. The cutting system as defined in claim 3 wherein the clamping device is further comprised of a collet clamp.
- 5 10. The cutting system as defined in claim 4 wherein the feeding device is further comprised of a pinch roller assembly disposed adjacent to the clamping device to thereby feed the elongate object to the clamping device.
- 10 11. The cutting system as defined in claim 10 wherein the pinch roller assembly is further comprised of:
- 15 a first wheel for supporting and forcing the cylindrical object to move to the clamping means when the clamping means is disengaged;
- a second wheel for applying a force to the cylindrical object to thereby hold it against the first wheel, thereby providing friction to push the cylindrical object to the clamping means; and
- 20 a lever arm coupled to the base at a pivoting end, and coupled to the second wheel at a movable end, wherein a spring means coupled between the lever arm and the base member provides the force of the second wheel.
- 25 12. The cutting system as defined in claim 6 wherein the system is further comprised of a sensor means for determining an extent of wear of the mechanical blade such that it can be replaced to thereby preserve
- 30 precision tolerances in a depth of a cut in the elongate object.
13. A method for forming at least one precision cut in an elongate object such as a catheter or a
- 35 guidewire, the apparatus including a clamping device, a means for feeding the elongate object to the clamping device, and a cutting device, wherein the

cutting device makes at least one precision cut in the elongate object which is generally at an angle or transverse relative to a lengthwise axis thereof, said method comprising the steps of:

- 5 (1) feeding the elongate object to the clamping device;
- (2) manipulating the elongate object into a position which is suitable for making the at least one precision cut therein;
- 10 (3) engaging the clamping device so as to securely hold the elongate object in the position which is suitable for cutting;
- (4) making the at least one precision cut in the elongate object;
- 15 (5) disengaging the clamping device; and
- (6) repeating steps (1) through (5) until all desired cuts in the elongate object are completed.

14. A system for forming precision cuts in a catheter, a guidewire, or other generally cylindrical objects, said system comprising:
- a base member;
 - a vertically movable member slidably coupled to the base member;
 - 25 a horizontally movable member having a spindle end and being slidably coupled to the vertically movable member;
 - at least one rotatable spindle disposed through the spindle end;
 - 30 at least one circular saw blade disposed coaxially on the spindle;
 - a drive means coupled to the at least one spindle for rotating the at least one circular saw blade;
 - 35 a clamping member coupled to the base member and disposed to thereby enable a clamping means to engage

the cylindrical object while the at least one circular saw blade makes an incision therethrough; and

means for feeding the cylindrical object to the clamping means.

5

15. The system as defined in claim 14 wherein the vertically

movable member has a first vertical coupling face and a first horizontal coupling face, and which is

10 slidably coupled to the base member at the first vertical face.

16. The system as defined in claim 15 wherein the horizontally

15 movable member has a second horizontal coupling face, wherein the horizontally movable member is slidably coupled at the second horizontal coupling face to the vertically movable member at the first horizontal coupling face.

20

17. The system as defined in claim 14 wherein the clamping means

is rotatably disposed within the clamping member to thereby enable the clamping member to rotate within

25 the clamping means and expose the circumference of the cylindrical object to the at least one circular saw blade.

18. The system as defined in claim 17 wherein the clamping means

30

is comprised of a collet clamp, and wherein the means for feeding the cylindrical object to the clamping means feeds the cylindrical object through a clamping hole in the collet clamp.

35

19. The system as defined in claim 14 wherein the clamping means

is comprised of:

a slotted horizontal surface for supporting the cylindrical object from below; and

- 5 a movable clamping member disposed above the slotted horizontal surface for applying force to the cylindrical object to thereby hold it against the slotted horizontal surface while the cylindrical is being cut.

- 10 20. The system as defined in claim 19 wherein the slotted horizontal surface is more specifically comprised of a single depression from which the cylindrical object can not easily move when force is being applied by the
15 movable clamping member.

21. The system as defined in claim 20 wherein the movable clamping member has a slot cut therein for engaging
20 the cylindrical object to more securely hold and prevent damage thereto.

22. The system as defined in claim 14 wherein the means for
25 feeding the cylindrical object to the clamping means is comprised of a pinch roller assembly disposed adjacent the clamping member to thereby feed the cylindrical object to the clamping means.

- 30 23. The system as defined in claim 22 wherein the pinch roller assembly is more specifically comprised of:
a first wheel for supporting and forcing the cylindrical object to move to the clamping means when
35 the clamping means is disengaged;
a second wheel for applying a force to the cylindrical object to thereby hold it against the

first wheel, thereby providing friction to push the cylindrical object to the clamping means; and

5 a lever arm coupled to the base at a pivoting end, and coupled to the second wheel at a movable end, wherein a spring means coupled between the lever arm and the base member provides the force of the second wheel.

10 24. The system as defined in claim 14 wherein the system further comprises a sensor means for determining an extent of wear of the at least one circular saw blade.

15 25. The system as defined in claim 24 wherein the sensor means is comprised of an electrical conduction sensing circuit coupled to the at least one circular saw blade and the cylindrical object, wherein the cylindrical object is conductive, and said circuit notifying a position
20 controlling means when an electrical circuit is complete when the at least one circular saw blade comes into contact with the electrically conductive cylindrical object.

25 26. The system as defined in claim 24 wherein the sensor means is comprised of a mechanical drag detection means coupled to the at least one circular saw blade by the driving means or the spindle.

30 27. The system as defined in claim 26 wherein the mechanical drag detection means is comprised of a rotation detector means which monitors rotation of the at least one circular saw blade, thereby determining
35 when contact is made by moving the spindle up and down while advancing toward the cylindrical object.

28. The system as defined in claim 26 wherein the mechanical drag detection means is comprised of a torque detector means which monitors a change in an amount of torque required to turn the at least one
5 circular saw blade.

29. The system as defined in claim 24 wherein the sensor means is
comprised of an optical detector means for detecting a
10 gap between the at least one circular saw blade and the cylindrical object.

30. The system as defined in claim 14 wherein the at least one
15 circular saw blade is more specifically comprised of a plurality of circular saw blades, wherein the saw blades are mounted in parallel and coaxially on the at least one spindle, and wherein each of the plurality of circular saw blades has a same diameter.

20 31. The system as defined in claim 30 wherein the clamping means
is comprised of a clamping member having:
a clamping surface wherein a depression is
25 disposed thereacross for partially receiving and holding straight the cylindrical object;
a plurality of slots extending from the clamping surface through to an oppositely facing back side;
a leaf spring coupled to the clamping surface for
30 forcing the cylindrical object into the depression and against the clamping surface;
a plurality of access holes in between the plurality of slots and extending from the back side through to the clamping surface; and
35 a plurality of push rods, a single rod disposed within each of the plurality of access holes to thereby lift the leaf spring from off the cylindrical

object when the cylindrical object must be manipulated.

- 5 32. The system as defined in claim 31 wherein the clamping member further comprises an actuatable means for pushing the push rods through the plurality of access holes when the cylindrical object is to be manipulated.
- 10 33. The system as defined in claim 14 wherein the system further comprises a position determining means for determining a position of the cylindrical object relative to the at least one circular saw blade so that the vertically
- 15 movable member and the horizontally movable member can be positioned correctly for making an incision.
- 20 34. The system as defined in claim 14 wherein the system further comprises a second horizontally movable member having a spindle end and a horizontal coupling face, wherein the horizontally movable member is slidably coupled at the horizontal coupling face to the vertically movable member at the first horizontal coupling face.
- 25 35. The system as defined in claim 34 wherein the system further comprises a spindle rotatably coupled to the spindle end of the second horizontally movable member, and
- 30 having a saw blade mounted coaxially on said spindle.
36. A method of cutting a catheter, guidewire or other cylindrical object when using a cutting device which
- 35 includes a vertically movable member with an associated horizontally movable member having a spindle coupled thereto, a circular saw blade

rotatably disposed on the spindle, a clamping assembly for holding the cylindrical object while the circular saw blade makes an incision therein, and means for advancing the cylindrical object to the clamping

5 means, the method comprising the steps of:

(1) providing a length of the cylindrical object to the means for advancing the cylindrical object to the clamping means, and advancing the cylindrical object;

10 (2) engaging the clamping means around the cylindrical object;

(3) advancing the horizontally movable member a desired cutting depth toward but beneath the cylindrical object;

15 (4) advancing the vertically movable member upward until the circular saw blade cuts the cylindrical object; and

(5) lowering the vertically movable member.

20 37. The method as defined in claim 36 wherein the method comprises the additional steps of:

1) disengaging the clamping means from around the cylindrical object;

25 2) advancing the cylindrical object through the clamping means; and

3) repeating steps 2) through 5) of claim 19.

30 38. The method as defined in claim 36 wherein the method

comprises the additional step of rotating the clamping means to thereby rotate the cylindrical object clamped therein and expose a different portion of the cylindrical object to the circular saw blade.

35

39. The method as defined in claim 36 wherein the method

comprises the additional step of rotating the clamping means and the means for advancing the cylindrical object to the clamping means to thereby rotate the cylindrical object clamped therein to expose a
5 different portion of the cylindrical object to the circular saw blade.

40. The method as defined in claim 36 wherein the method
10 comprises the additional step of:
1) disengaging the clamping means;
2) rotating the means for advancing the cylindrical object to thereby rotate the cylindrical object clamped therein to expose a different portion
15 of the cylindrical object to the circular saw blade;
and
3) engaging the clamping means.

41. A system for forming precision cuts in a
20 catheter, a guidewire, or other generally cylindrical objects, said system comprising:
a base member;
a horizontally movable member slidably coupled to
25 the base member;
a vertically movable member having a spindle end and being slidably coupled to the horizontally movable member;
at least one rotatable spindle disposed through
30 the spindle end;
at least one circular saw blade disposed coaxially on the spindle;
a drive means coupled to the at least one spindle for rotating the at least one circular saw blade;
35 a clamping member coupled to the base member and disposed to thereby enable a clamping means to engage

the cylindrical object while the at least one circular saw blade makes an incision therethrough; and

means for feeding the cylindrical object to the clamping means.

5

42. The system as defined in claim 41 wherein the vertically

movable member has a first vertical coupling face and a first horizontal coupling face, and which is

10 slidably coupled to the base member at the first vertical face.

43. The system as defined in claim 42 wherein the horizontally

15 movable member has a second horizontal coupling face, wherein the horizontally movable member is slidably coupled at the second horizontal coupling face to the vertically movable member at the first horizontal coupling face.

20

44. A system for forming precision cuts in a catheter, a guidewire, or other generally cylindrical objects, said system comprising:

25 a base member;

a lever arm coupled to the base member at a pivoting end and capable of horizontal and vertical movement of an opposite spindle end;

30 at least one rotatable spindle disposed through the spindle end;

at least one circular saw blade disposed coaxially on the spindle;

a drive means coupled to the at least one spindle for rotating the at least one circular saw blade;

35 a clamping member coupled to the base member and disposed to thereby enable a clamping means to engage

the cylindrical object while the at least one circular saw blade makes an incision therethrough; and

means for feeding the cylindrical object to the clamping means.

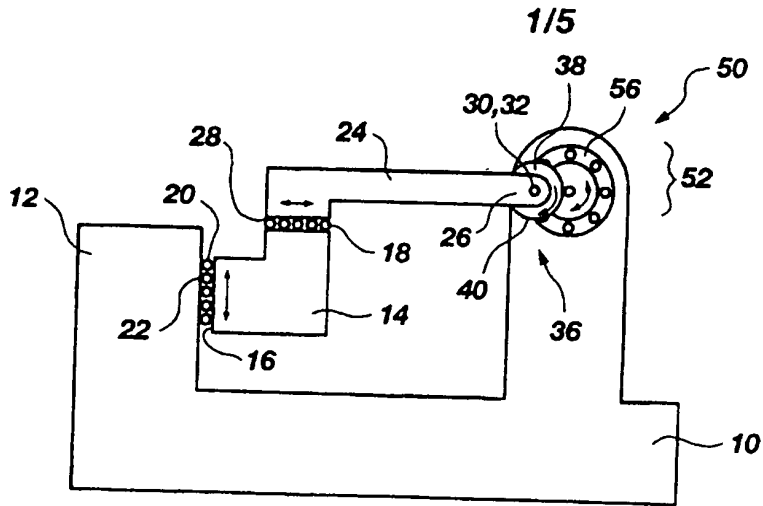


Fig. 1A

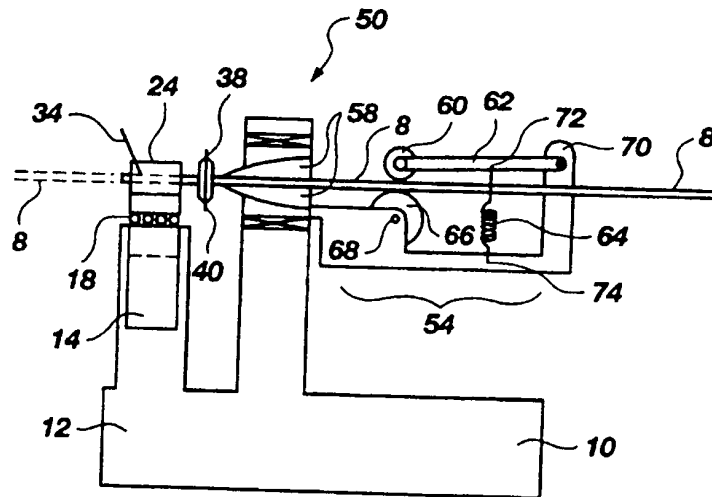


Fig. 1B

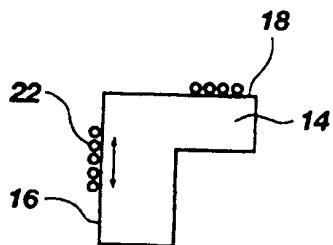


Fig. 2

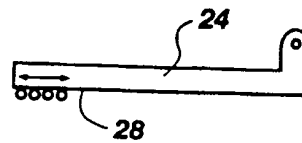


Fig. 3

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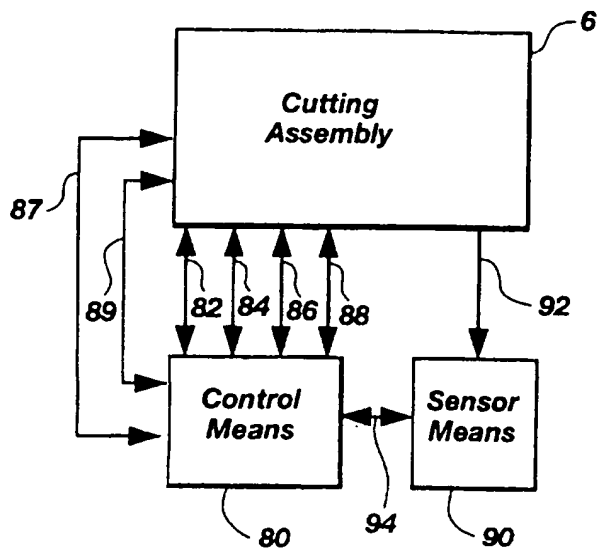


Fig. 4

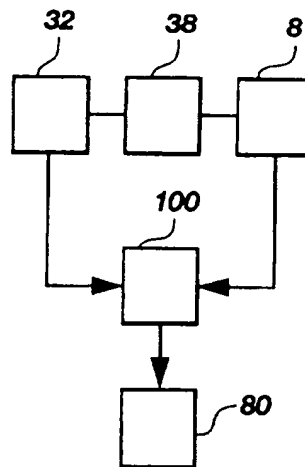


Fig. 5

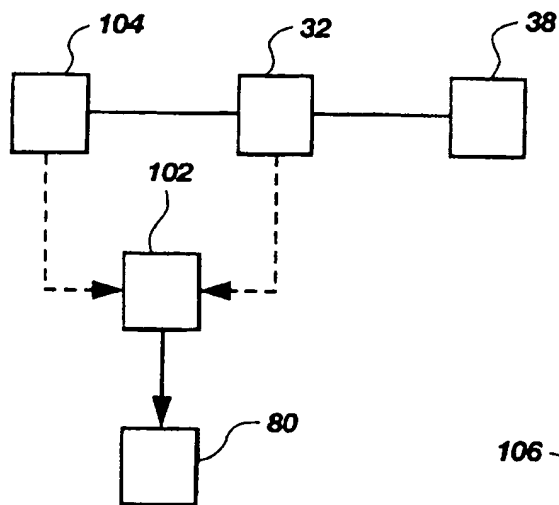


Fig. 6

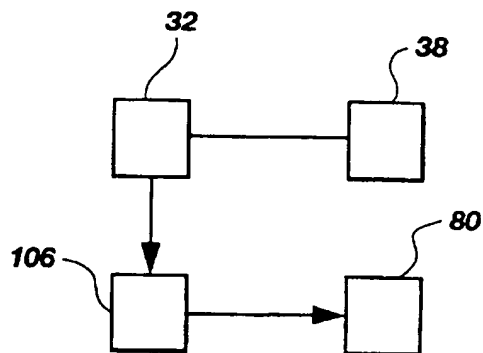
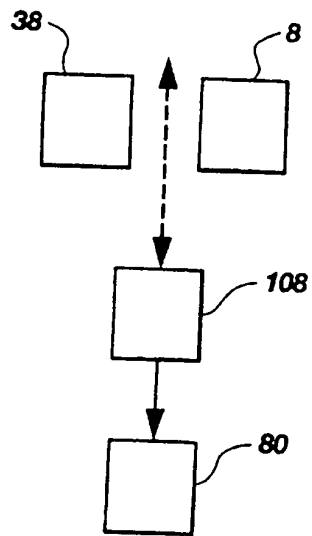
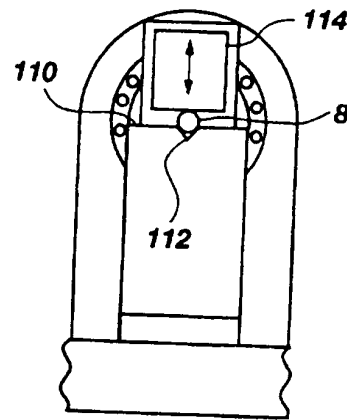
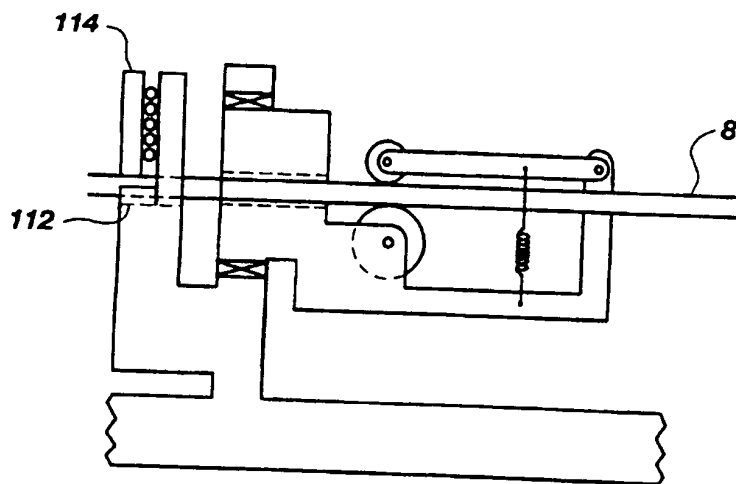
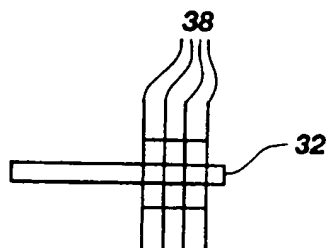
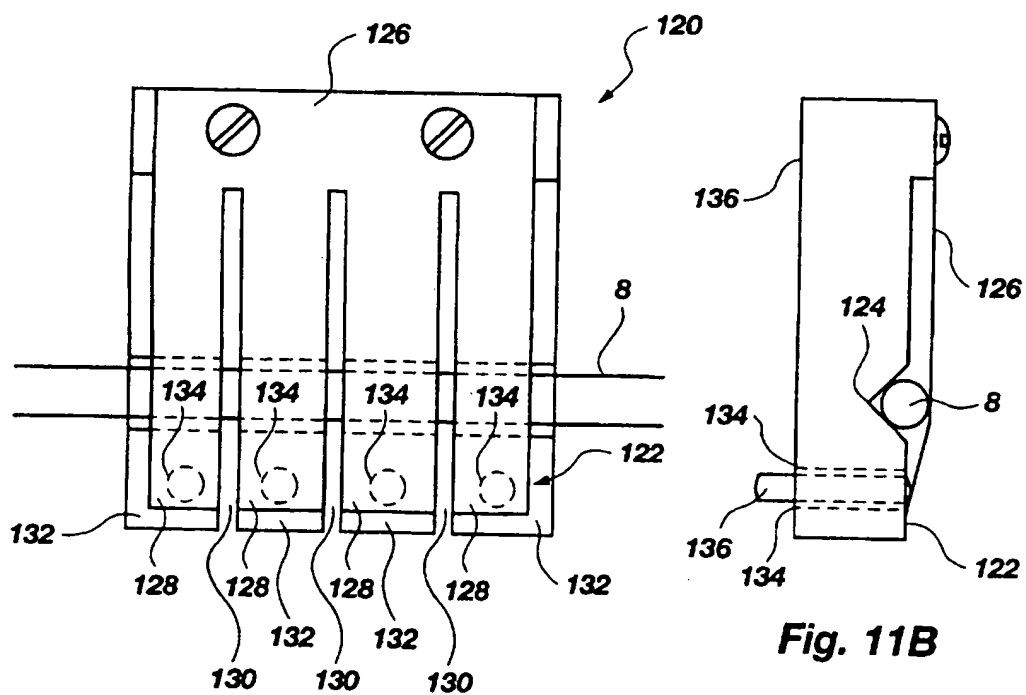


Fig. 7

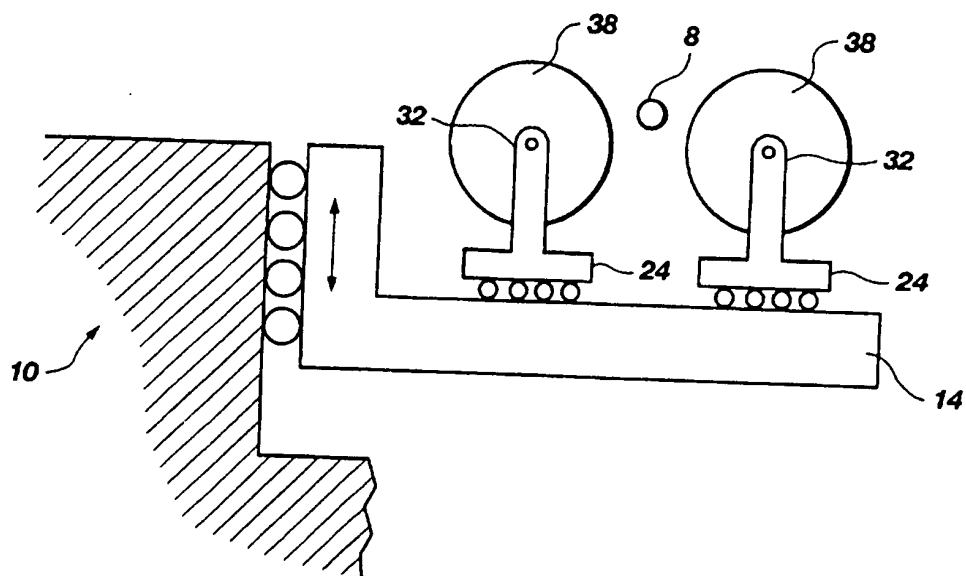
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**Fig. 8****Fig. 9A****Fig. 9B**

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**Fig. 10****Fig. 11A****Fig. 11B**

5/5

**Fig. 12**



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁶ : B26D 1/18, 3/08, 3/16, 5/42, 7/02, 7/26</p>	<p>A3</p>	<p>(11) International Publication Number: WO 98/10694</p> <p>(43) International Publication Date: 19 March 1998 (19.03.98)</p>
<p>(21) International Application Number: PCT/US97/16301</p> <p>(22) International Filing Date: 16 September 1997 (16.09.97)</p> <p>(30) Priority Data: 08/714,555 16 September 1996 (16.09.96) US</p> <p>(71) Applicant: SARCOS, INC. [US/US]; 360 Wakara Way, Salt Lake City, UT 84108 (US).</p> <p>(72) Inventors: JACOBSEN, Stephen, C.; 274 South 1200 East, Salt Lake City, UT 84102 (US). DAVIS, Clark, C.; 4569 Wallace Lane, Salt Lake City, UT 84124 (US).</p> <p>(74) Agents: THORPE, Calvin, E. et al.; Thorpe, North & Western, LLP, Suite 200, 9035 South 700 East, Sandy, UT 84070 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p> <p>(88) Date of publication of the international search report: 9 July 1998 (09.07.98)</p>
<p>(54) Title: METHOD AND APPARATUS FOR FORMING CUTS IN CATHETERS, GUIDEWIRES AND THE LIKE</p> <div data-bbox="470 1134 1153 1554"> </div> <p>(57) Abstract</p> <p>A catheter, guidewire or other cylindrical object cutting device having a base (10, 12), at least one circular saw blade (38) mounted on a spindle member (32), and a clamp (50) for manipulating the object (8) to be cut. The at least one circular saw blade is rotatably mounted on the spindle member. The spindle member is free to move vertically and horizontally with respect to the base to thereby control the location, size and depth of the cuts in a cylindrical object disposed adjacent thereto. The clamp holds the object as well as rotate it to expose the entire circumference of the object to the saw blade. By releasing the clamp, a pinch roller (60) can advance the object before the clamp is re-engaged to securely hold the object for cutting. Sensors (102, 106, 108) are also provided to enable detection of wear of the saw blade so as to signal needed replacement or adjustment of the saw blade.</p>		

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INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US97/16301

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : B26D 1/18, 3/08, 3/16, 5/42, 7/02, 7/26

US CL : Please See Extra Sheet

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 83/36, 49, 51,

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,574,670 A (JOHNSON et al) 11 March 1986, Figs. 1-14 and col. 3, line 67 - col. 8, line 56	1-9, 13-21, and 33-44
Y		10-12 and 22-32
Y	US 4,476,754 A (DUCRET) 16 October 1984, Figs. 1-3	10, 11, 22, and 23
Y	US 3,686,990 A (MARGOLIEN) 29 August 1972, Figs. 16 and 16A	12 and 24-29
Y	US 1,553,227 A (FEYK et al) 08 September 1925, Figs. 1-2	30-32
Y	WO 93/04722 A2 (HOLMES et al) 18 March 1993, whole document	1-44

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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Date of the actual completion of the international search

23 FEBRUARY 1998

Date of mailing of the international search report

16 MAR 1998

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/16301

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,315,906 A (FERENCZI et al) 31 May 1994, Figs. 1-37, col. 4, line 35 to col. 15, line 15	1-12, 16-35, and 41-44
Y	US 5,009,137 A (DANNATT) 23 April 1991, Fig. 11, col. 9, line 39 to col. 10, line 9	1-12, 16-35, and 41-44
Y	US 4,922,777 A (KAWABATA) 08 May 1990, Figs. 1, 2, and 9-18, col. 5, line 3 to col. 10, line 3	1-12, 16-35, and 41-44
Y	US 4,781,092 A (GAISER) 01 November 1988, Figs. 1-11, col. 3, line 43 to col. 6, line 23	1-12, 16-35, and 41-44
A	US 4,000,672 A (SITTERER et al) 04 January 1977, whole document	1-44
A	US 1,866,888 A (HAWLEY) 12 July 1932, Figs. 1-6	1-44

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/16301

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☒ No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/16301

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

83/36, 49, 51, 209, 210, 240, 248, 257, 282, 409, 418, 421, 457, 465, 466.1, 471.2, 471.3, 485, 486, 486.1, 556, 563, 733, 863, 864, 881, 886, 913, 924, 950; 269/254R, 902; 279/46.1

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

Group I, claims 1 and 2, drawn to a system for forming precision cuts and moving means for the cutting means.
Group II, claims 1, 3, 4, 9-11, and 13, drawn to a system and method for forming precision cuts and a feeding device.
Group III, claims 1, 3, 5, and 9, drawn to a system for forming precision cuts and a means for rotating the clamping device.
Group IV, claims 1, 6, and 7, drawn to a system for forming precision cuts and a selection of cutting means.
Group V, claims 1, 6, and 12, drawn to a system for forming precision cuts and sensor means.
Group VI, claims 1 and 8, drawn to a system for forming precision cuts and position of various elements.
Group VII, claims 14-16, drawn to a system for forming precision cuts, first vertical coupling face, and first and second horizontal coupling faces.
Group VIII, claims 14, 17, 18, and 36-39, drawn to a system and method for forming precision cuts and clamping member.
Group IX, claims 14, 19, 20, and 21, drawn to a system for forming precision cuts, a slotted horizontal surface, and a clamping member.
Group X, claims 14, 22, 23, 36, and 40, drawn to a system and method for forming precision cuts and a pinch roller assembly.
Group XI, claims 14, 24, and 25, drawn to a system for forming precision cuts, sensor means, and circuits.
Group XII, claims 14, 24, and 26-28, drawn to a system for forming precision cuts and mechanical drag detection means.
Group XIII, claims 14, 24, and 29, drawn to a system for forming precision cuts and optical detector means.
Group XIV, claims 14, 30, 31, and 32, drawn to a system for forming precision cuts, specifics of circular saws, and a clamping member and specifics of the clamping member.
Group XV, claims 14 and 33, drawn to a system for forming precision cuts and a position determining means.
Group XVI, claims 14, 34, and 35, drawn to a system for forming precision cuts and a second horizontally movable member.
Group XVII, claims 41-43, drawn to a system for forming precision cuts and a horizontally movable member slidably coupled to the base member.
Group XVIII, claim 44, drawn to a system for forming precision cuts and lever arm.

The inventions listed as Groups I-XVIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group I invention is in the moving means for the cutting means. The special technical feature of the Group II invention is in the feeding means. The special technical feature of the Group III invention is in the means for rotating the clamping device. The special technical feature of the Group IV invention is in the selection of the cutting means. The special technical feature of the Group V invention is in the sensor means. The special technical feature of the Group VI invention is in the position of the various elements. The special technical feature of the Group VII invention is in the first vertical coupling face and first and second horizontal coupling faces. The special technical feature of the Group VIII invention is in the clamping member rotating within the clamping means. The special technical feature of the Group IX invention is in the slotted horizontal surface and movable clamping member with a slot. The special technical feature of the Group X invention is in the pinch roller assembly. The special technical feature of the Group XI invention is in the sensor means and circuits. The special technical feature of the Group XII invention is in the mechanical drag detection means. The special technical feature of the Group XIII invention is in the optical detector means. The special technical feature of the Group XIV invention is in the specifics of the circular saws and the specifics of the clamping member. The special technical feature of the Group XV invention is in the position determining means. The special technical feature of the Group XVI invention is in the second horizontally movable member. The special technical feature of the Group XVII invention is in the horizontally movable member slidably coupled to the base member. The special technical feature of the Group XVIII invention is in the lever arm. Since the special technical feature of the Group I invention is not present in the claims of Groups II-XVIII; since the special technical feature of the Group II invention is not present in the claims of Groups I and III-XVIII; since the special technical feature of the Group III invention is not present in the claims of Groups I, II, and IV-XVIII; since the special technical feature of the Group IV invention is not present in the claims of Groups I-III and V-XVIII; since the special technical feature of the Group V invention is not present in the claims of Groups I-IV and VI-

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XVIII; since the special technical feature of the Group VI invention is not present in the claims of Groups I-V and VII-XVIII; since the special technical feature of the Group VII invention is not present in the claims of Groups I-VI and VIII-XVIII; since the special technical feature of the Group VIII invention is not present in the claims of Groups I-VII and IX-XVIII; since the special technical feature of the Group IX invention is not present in the claims of Groups I-VIII and X-XVIII; since the special technical feature of the Group X invention is not present in the claims of Groups I-IX and XI-XVIII; since the special technical feature of the Group XI invention is not present in the claims of Groups I-X and XII-XVIII; since the special technical feature of the Group XII invention is not present in the claims of Groups I-XI and XIII-XVIII; since the special technical feature of the Group XIII invention is not present in the claims of Groups I-XII and XIV-XVIII; since the special technical feature of the Group XIV invention is not present in the claims of Groups I-XIII and XV-XVIII; since the special technical feature of the Group XV invention is not present in the claims of Groups I-XIV and XVI-XVIII; since the special technical feature of the Group XVI invention is not present in the claims of Groups I-XV and XVII-XVIII; since the special technical feature of the Group XVII invention is not present in the claims of Groups I-XVI and XVIII; since the special technical feature of the Group XVIII invention is not present in the claims of Groups I-XVII, unity of invention is lacking.

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